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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

HO, UYEN T

ART UNIT

PAPER NUMBER -

3731

DATE MAILED: 05/21/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/664,970

Applicant(s)

BETELIA ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9-20 and 37-41 is/are pending in the application.
- 4a) Of the above claim(s) 38,40 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9-20,37 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Arguments

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. A new final rejection is made as follow.

Election/Restrictions

2. Applicant affirms the provisional election of Group I (readable on claim 1, 9-20, 37 and 39 in Paper No. 14 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (5,824,041) in view of Martinez et al. (5,453,090). Lenker et al. disclose a stent delivery system (fig. 19A-19D) including an elongate tubular outer sheath (254), a tubular prosthesis (P), an elongate bumper member (258) having a blunt edge disposed adjacent the proximal end of the prosthesis (P) preventing axial displacement of the

prosthesis upon retraction of the elongate tubular outer sheath (254), wherein the bumper member comprising an extension (252) extending from the bumper element, the extension including a lumen for receiving a guide wire there through. Lenker et al. fail to disclose the distal of the outer sheath (254) having a size for insertion into a blood vessel and terminating in a substantially atraumatic distal portion, wherein the distal end includes a plurality of flexible leaflets being deflectable from a closed position to an open configuration and the leaflets are connected to one another by weakened regions and the weakened regions being tearable upon retraction of the tubular member with respect to the prosthesis to allow the leaflets to be deflected towards the open position. Martinez et al. disclose a stent delivery system including an elongate tubular outer sheath having a distal end configured to prevent trauma when inserted into a vessel, the distal end including a plurality of flexible leaflets being deflectable from a closed position to an open configuration and the leaflets are connected to one another by weakened regions and the weakened regions being tearable for deploying a stent (col. 4, lines 6-64). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a plurality of flexible leaflets as disclosed by Martinez et al. into the distal end of the tubular outer sheath of Lenker et al.'s stent delivery system in order to prevent the distal end of the outer sheath damaging the wall of a blood vessel.

5. Claims 11-20, 37 and 39 rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. '041 in view of Martinez et al. '090 further in view of Estrada et al. (6,193,686), Lodin et al. (5,460,608) and Thornton (5,891,090).

In regard to claims 11-19, 37 and 39, Lenker et al. in view of Martinez et al. disclose all the limitation of the claims except for a presence of a bumper element that includes a helical coil. Lodin et al. (fig. 1), Thornton (fig. 1) and Estrada et al. (fig. 1) disclose a catheter system including a helical coil for reinforcing the tubular catheter to prevent the tubular catheter from collapsing or breaking throughout its length and resistant to buckling or kinking. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a coil into the stent delivery system of Lenker et al. in view of Martinez in order to reinforce the bumper element and enhance the strength and pushability of the bumper element.

In regard to claim 20, it is known in the art to having a radiopaque marker on a portion of catheter, stent or any member that is inserted into a body lumen in order to track the location of the inserted member in the body lumen. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a radiopaque marker on the bumper element of Lenker et al. in view of Martinez et al.'s implant system in order to locate the bumper element in a body lumen.

6. Claims 1, 9-18, 20, 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sepetka et al. (5,814,062) in view of Martinez et al. (5,453,090). Sepetka et al. disclose an implant delivery system including an elongate tubular member (4), a bumper element (26) comprising helical coil (36), and a prosthesis with a coiling tubular shape (28). Sepetka et al. fail to disclose the elongate tubular member having a distal end including a plurality of leaflets and the leaflets connected to each other by weakened regions. Martinez et al. disclose a implant delivery system including

an elongate tubular outer sheath having a distal end configured to prevent trauma when inserted into a vessel, the distal end including a plurality of flexible leaflets being deflectable from a closed position to an open configuration and the leaflets are connected to one another by weakened regions and the weakened regions being tearable for deploying an implant (col. 4, lines 6-64). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a plurality of flexible leaflets as disclosed by Martinez et al. into the distal end of the tubular outer sheath of Sepetka et al.'s implant delivery system in order to prevent the distal end of the outer sheath damaging the wall of a blood vessel.

In regard to claim 20, it is known in the art to having a radiopaque marker on a portion of catheter, stent or any member that is inserted into a body lumen in order to track the location of the inserted member in the body lumen. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a radiopaque marker on the bumper element of Sepetka et al.'s implant delivery system in order to locate the bumper element in a body lumen.

Response to Arguments

7. Applicant's arguments filed 5/9/2003 have been fully considered but they are not persuasive. Applicants argue that Lenker et al. and Martinez et al. reference fail to disclose a bumper member with a distal end "having a blunt edge disposed adjacent the proximal end of the prosthesis for preventing axial displacement of the prosthesis upon retraction of the tubular member with respect to the bumper member." Examiner

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respectfully disagree. Lenker et al. disclose a bumper member or an anchor member (258) having a distal end including a blunt edge as illustrated below. Note: in this case blunt edge does not mean "blunt tip."

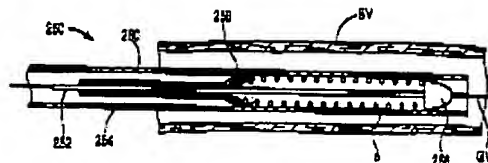


FIG. 19A

Blunt edge (in red ink)

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3977 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731
May 19, 2003



MICHAEL J. MILANO
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